VERMONT

Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 06/10/08

Board Members:

Michael Scovner, M.D., Chair
Andrew Miller, R. Ph.
Norman Ward, M.D.
Richard Harvie, R. Ph.
Lynne Vezina, R.Ph.
Stuart Graves, M.D.

Staff:

Ann Rugg, OVHA
Diane Neal, R.Ph., (MHP)
Nancy Hogue, Pharm.D. (MHP)
Nancy Miner, (MHP)
Stacey Baker, OVHA
Judy Jamieson, OVHA
Robin Farnsworth, OVHA
Jennifer Mullikin, OVHA

Guests:

Bob Clark, Novartis
Carl Pepe, GSK
Chris Enfanto, Takeda
Christy Owens, Novartis
Greg Butler, Specialty Script Pharmacy
Helen Pepin, Takeda
James Kokoszyna, Allergan
Jenifer Buttle, Merck
Keith White, Genentech
Linda Guggenheim, Merck
Mario Carnovale, Novartis
Mark Kaplan, Abbott
Matt Badalucco, Merck
Mike DeOrsey, Abbott
Pam Sardo, Pharm D. Abbott
Rob Mann, GSK
Scott Strenio, APS Healthcare
Tracy Wall, Merck

Norman Ward, M.D., Acting Chair, called the meeting to order at 7:02 p.m. at the DUR Board meeting site in Williston.

1. Executive Session:

- An executive session was held from 6:30 until 7:00 p.m. to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2).

2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table.
- The May 2008 meeting minutes were accepted as printed.

Public Comment: No public comment.

3. OVHA Pharmacy Administration Updates: *Ann Rugg - Deputy Director, OVHA*

- Nothing to report this month.

4. Physician Update: *Dr. Scott Strenio, APS Healthcare*

Chronic Care Management Program: Dr. Strenio from APS presented an overview of the Program that applies to approximately 25,000 beneficiaries with one of eleven chronic conditions.

5. Follow-up items from Previous Meeting: *Diane Neal, R.Ph., MedMetrics Health Partners (MHP)*

- Soliris® (eculizumab) for PNH:
  Some questions were raised by the manufacturer's representative about our newly updated criteria. The criteria will be reviewed again and expert input will be requested.

Public Comment: No public comment.

Board Decision: None needed.

6. Clinical Update: Drug Reviews: *Diane Neal, R.Ph.(MHP)*
(Public comment prior to Board action)

Note: All drug/criteria decisions will be reflected in the next PDL and/or Clinical Criteria update.

- Combigan® (brimonidine tartrate/timolol maleate) Ophthalmic Solution: Recommended for addition to the PDL as preferred for reduction of elevated intraocular pressure.

Public Comment: *James Kokoszyna, Allergan* – Commented that ophthamologists generally start with a single agent product before prescribing Combigan®.

Board Decision: The Board approved the MHP recommendations as described. The Board requested that Combigan® utilization be evaluated in six months to be sure that it was not being utilized as first line therapy.

- Simcor® (simvastatin/extended-release niacin): Recommended for addition to the PDL as preferred for reduction of cholesterol and triglycerides. A quantity limit of one tablet per day was recommended.

Public Comment: Pam Sardo, Pharm D., Abbott – Commented on the efficacy, tolerability and side effects of Simcor®.
Mark Kaplan, Abbott – Commented that the use of Simcor® may reduce the use of more expensive statins.

Board Decision: The Board approved the MHP recommendations noted above. The Board requested a notation in the clinical criteria manual that therapy with simvastatin alone is recommended to be used first line.

- Tekturna HCT® (aliskiren/hydrochlorothiazide): Recommended for addition to the PDL as preferred after clinical criteria are met with the same approval criteria as Tekturna®, that is, the patient has a diagnosis of hypertension and the patient has had a documented side effect, allergy, or treatment failure with an angiotensin receptor blocker (ARB) or an ARB combination product. *Note:* Approval of a preferred ARB requires a documented side effect, allergy, or treatment failure with an angiotensin converting enzyme (ACE) inhibitor. A quantity limit of one tablet per day was recommended.

Public Comment: Bob Clark, Novartis – Offered to answer any questions from the DUR Board.

Board Decision: The Board approved the MHP recommendations as described.

7. Review of Newly-Developed/Revised Clinical Coverage Criteria: *Diane Neal, R.Ph, (MHP)*
(Public comment prior to Board action)

- Constipation: Chronic (expanded indication for Amitiza® (lubiprostone):
  A new 8 mcg dosage form was recently approved by the FDA for the treatment of irritable bowel syndrome with constipation. It was recommended that the category be expanded from Constipation: Chronic to Constipation: Chronic or IBS-C and that this dosage form be PA required with the same criteria as for the previously reviewed 24 mcg dosage form. Criteria for approval would that the patient is a woman and has a diagnosis or irritable bowel syndrome with constipation (IBS-C) and the patient has had documented treatment failure to lifestyle and dietary modification (increased fiber and fluid intake and increased physical activity) and the patient has had documented side effect, allergy or treatment failure to a 1 week trial each of at least 2 preferred chronic constipation laxatives. A quantity limit of 2 capsules per day was recommended.

Public Comment: Chris Enfanto, Takeda – Commented on the difference between chronic constipation and irritable bowel syndrome with constipation.

Board Decision: The renamed category and revised clinical criteria were unanimously accepted as presented.

8. Drug Classes - Reviews:

- Urinary Antispasmodics (and new drug review Sanctura XR® (trospium XR)):
  A review of the drug class was presented. The new dosage form of Sanctura XR® was also presented and it was recommended to be added as a preferred product equally preferred with the other preferred long acting agents. A quantity limit of 1 tablet per day was recommended. Quantity limits for all other long acting agents was also recommended. It was recommended that the criteria for Oxytrol® be revised to a need for a transdermal product (unable to use oral medication).

Public Comment: No public comment.

Board Decision: The revised clinical criteria were unanimously accepted.

9. RetroDUR: *Diane Neal, R.Ph, (MHP)*

- Asthma Medication Therapy-Pre and Post Emergency Room or Inpatient Hospital Admission:
  A study prepared by MedMetrics Pharmacy Practice Resident Phuong Pham, Pharm.D. entitled "Asthma Prescribing Trends in Vermont Medicaid Patients" was presented. This was a retrospective observational study. Adherence to maintenance medication was poor both pre and post admission. There was discussion among the Board members of the need to work collaboratively with APS and the Chronic Care Management Program. Additionally, interest was expressed in providing education to pharmacists and the possibility of coding to flag frequent fill of SABA (short acting beta agonist).

Public Comment: No public comment.

Board Decision: None needed.

- Nutritionals, enteral: Although a PA form has existed for some time, an actual listing of the managed category was never established in the Clinical Criteria Manual. The criteria listed on the

PA form were also felt to be vague. A managed category with criteria and a revised PA form were presented. The definition of weight loss was refined.

Public Comment: No public comment.

Board Decision: The new managed category, clinical criteria and PA form were approved as presented.

- Suboxone®/Subutex®: Updated utilization data was presented. It was recommended that PA be required for all current users who are qualifying for the medication through previously established "grandfathering". Due to the large number of users this will have to be carried out in a phased in manner over an extended period of time so as to not overwhelm the Clinical Call Center.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the recommendations as presented.

10. New Drug Product Plan Exclusions: *Diane Neal, R.Ph, (MHP)*

- New drug products released on the market are reviewed every 2 weeks by MedMetrics Health Partners to determine pharmacy benefit coding according to the current PDL. As approved by the DUR Board, drug products that appear to be illogical combinations, kits containing non-drug items or very expensive dosage forms where inexpensive alternatives exist are blocked. The presented table highlights drug products blocked from drug files dated 05/22/08 - 06/05/08. DUR Board members were asked to comment if they felt that a drug product should not be blocked.

Public Comment: No public comment.

Board Decision: None needed.

11. Updated New-to-Market Monitoring Log: *Diane Neal, R.Ph, (MHP)*

- This log shows new entries in the market highlighted in red. The log is informational only. Suggested dates for review are to be used as a guide only. The actual date of review will depend on the complexity of the agenda.

Public Comment: No public comment.

12. General Announcements: *Diane Neal, R.Ph, (MHP)*
FDA Safety Alerts

- Inosine Monophosphate Dehydrogenase Inhibitors (IMPDH) Immunosuppressants - fetal harm/spontaneous abortion: FDA is aware of reports of infants born with serious congenital anomalies, including microtia and cleft lip and palate, following exposure to mycophenolate mofetil (MMF) during pregnancy. In most cases, the mothers were taking MMF following an organ transplant to prevent organ rejection. However, some mothers taking MMF were being treated for immune-mediated conditions such as systemic lupus erythematosus (SLE) and erythema multiforme. A look back is already in place for Myfortic and Prenatal Vitamins and a mailing was sent to selected physicians previously. The alert will be posted on the OVHA pharmacy web site.

Public Comment: No public comment.

Board Decision: None needed.

- Enbrel-infection: Amgen and Wyeth Pharmaceuticals informed healthcare professionals of revisions to prescribing information for Enbrel. The revisions include a BOXED WARNING about infections, including serious infections leading to hospitalization or death that have been observed in patients treated with Enbrel. Infections have included bacterial sepsis and tuberculosis. The communication will be posted on the OVHA pharmacy web site.

Public Comment: No public comment.

Board Decision: None needed.

- TNF Blockers – Safety review (development of cancers): The FDA issued an early communication about an ongoing safety review to inform healthcare professionals that the Agency is investigating a possible association between the use of Tumor Necrosis Factor (TNF) blockers and the development of lymphoma and other cancers in children and young adults. The FDA is investigating approximately 30 reports of cancer in children and young adults. The communication will be posted on the OVHA pharmacy web site.

Public Comment: No public comment.

Board Decision: None needed.

13. Adjourn: Meeting adjourned at 9:26 p.m.

Next DUR Board Meeting
Tuesday, September 09, 2008
7:00 - 9:00 p.m.*
EDS Building, OVHA Conference Room
312 Hurricane Lane, Williston, VT
(Entrance is in the rear of the building)

* The Board meeting will begin at 6:30 p.m. and the Board will vote to adjourn to Executive Session to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2). The Executive Session is closed to the public.